



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

June 30, 1988

#22

Mr. Ronald Wilson  
Health Assessment Policy Staff  
Office of Health Affairs  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,543,954, issued October 1, 1985, was filed on June 27, 1988, under Title II of Public Law 98-417.

The assistance of your Office is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC 156 (g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product and method of using a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC 156(d) (2) (A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 USC 156.

C.E. Van Horn

Charles E. Van Horn  
Deputy Solicitor  
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